

## CLAIMS:

1. A catheter assembly comprising:
  - a catheter shaft, the catheter shaft having a length and an outer surface;
  - a balloon, the balloon comprising a proximal balloon waist, a distal balloon
  - 5 waist and a body portion there between, the balloon having an expanded state and a unexpanded state, in the expanded state the body portion having an expanded diameter and in the unexpanded state the body portion having an unexpanded diameter that is less than the expanded diameter; and
  - a proximal collar and a distal collar, the proximal collar engaged to the
  - 10 catheter shaft and the distal collar engaged to the catheter shaft, each collar having a nonactivated state and an activated state, in the nonactivated state the distal balloon waist being rotatable about the distal collar and the proximal balloon waist being rotatable about the proximal collar, in the activated state the proximal collar being expanded to sealingly engage the proximal balloon waist and the distal collar being expanded to sealingly engage
  - 15 the distal balloon collar.
2. The catheter assembly of claim 1 wherein the collars are actuated between the nonactivated state and the activated state by exposure to an electric current.
3. The catheter assembly of claim 2 further comprising at least one electrically
- 20 conductive member, each collar being in electronic communication with the at least one electrically conductive member.
4. The catheter assembly of claim 3 further comprising a source of electrical current, the source being in electronic communication with the at least one electrically conductive member.
5. The catheter assembly of claim 4 wherein the catheter shaft comprises an inner
- 25 catheter shaft and an outer catheter shaft, the proximal collar being engaged to a portion of the outer catheter shaft and the distal collar being engaged to a portion of the inner catheter shaft.

6. The catheter assembly of claim 5 wherein the inner catheter shaft is at least partially constructed of at least one material of the group consisting of: HDPE, Pebax, Polyamide, Nylon, multilayer extrusions and any combination thereof.
7. The catheter assembly of claim 6 wherein the at least one electrically conductive member is at least partially enclosed by the inner catheter shaft.
8. The catheter assembly of claim 7 wherein the at least one electrically conductive member is co-extruded with the at least one material of the inner catheter shaft.
9. The catheter assembly of claim 5 wherein the outer catheter shaft is at least partially constructed of at least one material of the group consisting of: Pebax, Nylon, nanocomposites, multilayer extrusions, and any combination thereof.
10. The catheter assembly of claim 9 wherein the at least one electrically conductive member is at least partially enclosed by the outer catheter shaft.
11. The catheter assembly of claim 10 wherein the at least one electrically conductive member is co-extruded with the at least one material of the outer catheter shaft.
12. The catheter assembly of claim 3 wherein the at least one electrically conductive member is at least partially constructed of at least one material of the group consisting of: gold, silver, platinum, nitinol, and any combination thereof.
13. The catheter assembly of claim 5 wherein the outer catheter shaft is disposed about a portion of the inner catheter shaft, an inflation lumen in fluid communication with an interior of the balloon body being defined by a space between the inner catheter shaft and the outer catheter shaft.
14. The catheter assembly of claim 13 wherein the portion of the outer catheter shaft is disposed about a support ring, the inner catheter shaft extending through the support ring.
15. The catheter assembly of claim 7 wherein the support ring is at least partially constructed of at least one material of the group consisting of: stainless steel, Nitinol, acetyl, PI, HDPE, LX2/TR55, nanocomposites, ceramics, and any combinations thereof.
16. The catheter assembly of claim 1 further comprising at least one marker band the at least one marker band being engaged to a portion of the catheter shaft.
17. The catheter assembly of claim 16 wherein the at least one marker band is at least partially radiopaque.

18. The catheter assembly of claim 16 wherein the at least one marker band is detectable by at least one imaging modality selected from the group consisting of X-Ray, MRI ultrasound and a combination thereof.
19. The catheter assembly of claim 1 wherein the balloon is constructed of at least one member of the group consisting of: Pebax, Nylon, PET, polyester, polyolefin copolymer) and any combination thereof.
20. The catheter assembly of claim 3 wherein the at least one conductive member is positioned within at least a portion of the balloon.
21. The catheter assembly of claim 20 wherein the at least one electrically conductive member is co-extruded within the at least a portion of the balloon.
22. The catheter assembly of claim 3 wherein the proximal collar and the distal collar are comprised of electro-active polymer (EAP) material.
23. The catheter assembly of claim 22 wherein the EAP material is selected from at least one member of the group consisting of: Poly-pyrrole (PPY), Poly-Aniline (PAni), Poly-Thiophene (PTH), Poly-Paraphenylene Vinylene (PPV), Nafion, Bucky paper, and any combination thereof.
24. The catheter assembly of claim 22 wherein when the proximal collar and the distal collar are exposed to the electric current the EAP material in each collar expands about 0.5% to about 20 percent.
25. The catheter assembly of claim 22 wherein the proximal collar and the distal collar are further comprised of at least one electrically conductive marker, the EAP material being a layer of material engaged to at least a portion of a surface of the at least one electrically conductive marker.
26. The catheter assembly of claim 25 wherein the at least one electrically conductive marker is constructed of at least one material of the group consisting of gold, platinum, silver, nitinol, and any combination thereof.
27. The catheter assembly of claim 26 wherein the at least one electrically conductive marker is in direct contact with a portion of the at least one electrically conductive member which radially extends through at least one opening in the catheter shaft.

28. The catheter assembly of claim 1 further comprising a distal hub, the distal hub fixedly engaged to the catheter shaft distal of the distal collar.
29. The catheter assembly of claim 1 further comprising a proximal hub, the proximal hub fixedly engaged to the catheter shaft proximal of the proximal collar.
- 5 30. The catheter assembly of claim 1 further comprising a secondary guidewire housing, the secondary guidewire housing comprising a substantially tubular member engaged to the balloon, the secondary guidewire housing defining a secondary guidewire lumen through which a secondary guidewire may be slidingly positioned.
31. The catheter assembly of claim 30 wherein the secondary guidewire housing is at  
10 least partially constructed of at least one material of the group consisting of: metal, polymer, natural rubber, silicone, urethanes, Pebax, HDPE, and any combination thereof.
32. The catheter assembly of claim 30 wherein the secondary guidewire housing is integral with the balloon.
33. The catheter assembly of claim 30 wherein the secondary guidewire housing is  
15 engaged to an external surface of the balloon.
34. The catheter assembly of claim 33 wherein the secondary guidewire housing is welded to the external surface of the balloon.
35. The catheter assembly of claim 30 wherein the secondary guidewire housing extends  
from a proximal end of the balloon body to an intermediate region of the balloon body.
- 20 36. The catheter assembly of claim 30 wherein the secondary guidewire has a length at least as long as the balloon body.
37. The catheter assembly of claim 30 further comprising a balloon expandable stent, the stent being expandable from an unexpanded configuration to an expanded configuration, in the unexpanded configuration the stent being disposed about at least a  
25 portion of the balloon body.
38. The catheter assembly of claim 37 wherein at least a proximal portion of the stent overlays at least a portion of the secondary guidewire housing.
39. The catheter assembly of claim 38 wherein the stent comprises a plurality of interconnected members, wherein adjacent members define openings there between, one of

the openings being a secondary opening through which the secondary guidewire radially extends.

40. The catheter assembly of claim 39 wherein a distal end of the secondary guidewire housing extends radially through the secondary opening.

5 41. The catheter assembly of claim 37 wherein at least a portion of the stent is coated with at least one therapeutic agent.

42. The catheter assembly of claim 41 wherein the at least one therapeutic agent is at least one non-genetic therapeutic agent selected from at least one member of the group consisting of: anti-thrombogenic agents such as heparin, heparin derivatives, urokinase, and  
 10 PPACK (dextrophenylalanine proline arginine chloromethylketone); anti-proliferative agents such as enoxaprin, angiopeptin, monoclonal antibodies capable of blocking smooth muscle cell proliferation, hirudin, and acetylsalicylic acid; anti-inflammatory agents such as dexamethasone, prednisolone, corticosterone, budesonide, estrogen, sulfasalazine, and mesalamine; antineoplastic/antiproliferative/anti-miotic agents such as paclitaxel, 5-  
 15 fluorouracil, cisplatin, vinblastine, vincristine, epothilones, endostatin, angiostatin and thymidine kinase inhibitors; anesthetic agents such as lidocaine, bupivacaine and ropivacaine; anti-coagulants such as D-Phe-Pro-Arg chloromethyl keton, an RGD peptide-containing compound, heparin, antithrombin compounds, platelet receptor antagonists, anti-thrombin antibodies, anti-platelet receptor antibodies, aspirin, prostaglandin inhibitors,  
 20 platelet inhibitors and tick antiplatelet peptides; vascular cell growth promoters such as growth factor inhibitors, growth factor receptor antagonists, transcriptional activators, and translational promoters, vascular cell growth inhibitors such as growth factor inhibitors, growth factor receptor antagonists, transcriptional repressors, translational repressors, replication inhibitors, inhibitory antibodies, antibodies directed against growth factors,  
 25 bifunctional molecules consisting of a growth factor and a cytotoxin; bifunctional molecules consisting of an antibody and a cytotoxin; cholesterol-lowering agents; vasodilating agents; and agents which interfere with endogenous vasoactive mechanisms, and any combinations thereof.

43. The catheter assembly of claim 41 wherein the at least one therapeutic agent is at  
 30 least one genetic therapeutic agent selected from at least one member of the group

- consisting of: anti-sense DNA and RNA; DNA coding for anti-sense RNA, tRNA or rRNA to replace defective or deficient endogenous molecules; angiogenic factors including growth factors such as acidic and basic fibroblast growth factors, vascular endothelial growth factor, epidermal growth factor, transforming growth factor  $\alpha$  and  $\beta$ , platelet-derived endothelial growth factor, platelet-derived growth factor, tumor necrosis factor  $\alpha$ , hepatocyte growth factor and insulin like growth factor; cell cycle inhibitors including CD inhibitors, thymidine kinase ("TK") and other agents useful for interfering with cell proliferation; at least one of the family of bone morphogenic proteins ("BMP's") such as BMP-2, BMP-3, BMP-4, BMP-5, BMP-6 (Vgr-1), BMP-7 (OP-1), BMP-8, BMP-9, BMP-10, BMP-11, BMP-12, BMP-13, BMP-14, BMP-15, and BMP-16. Any of BMP-2, BMP-3, BMP-4, BMP-5, BMP-6 and BMP-7; dimeric proteins such as homodimers, heterodimers, or combinations thereof, alone or together with other molecules; molecules capable of inducing an upstream or downstream effect of a BMP such as "hedgehog" proteins, or the DNA's encoding them and any combinations thereof.
44. The catheter assembly of claim 41 wherein the at least one therapeutic agent is at least one type of cellular material selected from at least one member of the group consisting of: cells of human origin (autologous or allogeneic); cells of non-human origin (xenogeneic) and any combination thereof.
45. The catheter assembly of claim 44 wherein the cellular material is selected from at least one member of the group consisting of: side population cells; lineage negative cells; lineage negative CD34<sup>-</sup> cells; lineage negative CD34<sup>+</sup> cells; lineage negative cKit<sup>+</sup> cells; mesenchymal stem cells; cord blood cells; cardiac or other tissue derived stem cells; whole bone marrow; bone marrow mononuclear cells; endothelial progenitor cells; satellite cells; muscle derived cells; go cells; endothelial cells; adult cardiomyocytes; fibroblasts; smooth muscle cells; cultures of mesenchymal stem cells with 5-aza forces differentiation into cardiomyocytes; adult cardiac fibroblasts + 5-aza; genetically modified cells; tissue engineered grafts; MyoD scar fibroblasts; Pacing cells; embryonic stem cell clones; embryonic stem cells; fetal or neonatal cells; immunologically masked cells; tissue engineered grafts; genetically modified cells; teratoma derived cells and any combinations thereof.

46. The catheter assembly of claim 41 wherein the at least one therapeutic agent comprises at least one polymer coating, the at least one coating selected from at least one member of the group consisting of: polycarboxylic acids; cellulosic polymers, including cellulose acetate and cellulose nitrate; gelatin; polyvinylpyrrolidone; cross-linked
- 5 polyvinylpyrrolidone; polyanhydrides including maleic anhydride polymers; polyamides; polyvinyl alcohols; copolymers of vinyl monomers such as EVA; polyvinyl ethers; polyvinyl aromatics; polyethylene oxides; glycosaminoglycans; polysaccharides; polyesters including polyethylene terephthalate; polyacrylamides; polyethers; polyether sulfone; polycarbonate; polyalkylenes including polypropylene, polyethylene and high molecular
- 10 weight polyethylene; halogenated polyalkylenes including polytetrafluoroethylene; polyurethanes; polyorthoesters; proteins; polypeptides; silicones; siloxane polymers; polylactic acid; polyglycolic acid; polycaprolactone; polyhydroxybutyrate valerate and blends and copolymers thereof; coatings from polymer dispersions such as polyurethane dispersions (BAYHDROL<sup>®</sup>, etc.), fibrin, collagen and derivatives thereof; polysaccharides
- 15 such as celluloses, starches, dextrans, alginates and derivatives; hyaluronic acid; squalene emulsions; polyacrylic acid, a copolymer of polylactic acid and polycaprolactone; medical-grade biodegradable materials such as PGA-TMC, Tyrosine-Derived Polycarbonates and arylates; polycaprolactone co butyl acrylate and other co polymers; Poly-L-lactic acid blends with DL-Lactic Acid; Poly(lactic acid-co-glycolic acid); polycaprolactone co PLA;
- 20 polycaprolactone co butyl acrylate and other copolymers; Tyrosine-Derived Polycarbonates and arylate; poly amino acid; polyphosphazenes; polyiminocarbonates; polydimethyltrimethylcarbonates; biodegradable CA/PO<sub>4</sub>'s; cyanoacrylate; 50/50 DLPLG; polydioxanone; polypropylene fumarate; polydepsipeptides; macromolecules such as chitosan and Hydroxylpropylmethylcellulose; surface erodible material; maleic anhydride
- 25 copolymers; zinc-calcium phosphate; amorphous polyanhydrides; sugar; carbohydrate; gelatin; biodegradable polymers; and polymers dissolvable in bodily fluids; A block copolymers; B block copolymers and any combinations thereof.
47. The catheter assembly of claim 4 further comprising an inflation fluid, the inflation fluid being injected into the balloon in order to expand the balloon from the unexpanded
- 30 state to the expanded state, the inflation fluid being electrically conductive.

48. The catheter assembly of claim 47 wherein the proximal collar, the distal collar, the at least one electrically conductive member, the inflation fluid and the source of electric current forming an electric circuit through which the electric current flows to place the collars in the activated state.

5 49. A method of imparting selective rotatability and sealability to a balloon of a balloon catheter comprising the steps of:

providing a catheter shaft having at least one electrically conductive member, a first portion of the at least one electrically conductive member being externally exposed through an outer surface of the catheter shaft and a second portion of the at least one electrically conductive member being externally exposed through the outer surface of the catheter shaft;

providing a balloon;

engaging a proximal waist of the balloon to a first collar, the first collar at least partially constructed of EAP material;

15 engaging a distal waist of the balloon to a second collar, the second collar at least partially constructed of EAP material;

disposing the balloon about the catheter shaft such that an interior surface of the first collar is in electronic communication with the first portion of the at least one electrically conductive member and an interior surface of the second collar is in electronic communication with the second portion of the at least one electrically conductive member;

20 selectively providing an electric current to the at least one electrically conductive member such that when the current is supplied to the at least one electrically conductive member the first collar and the second collar are sealingly engaged to the outer surface of the catheter shaft and when the current is not supplied to the at least one electrically conductive member the first collar and the second collar are free to rotate about the outer surface of the catheter shaft.

50. A catheter assembly comprising:

a catheter shaft, the catheter shaft having a length and an outer surface;

30 a balloon the balloon comprising a proximal balloon waist, a distal balloon waist and a body portion there between, the body portion being expandable between an



unexpanded diameter and an expanded diameter, wherein the expanded diameter is greater than the unexpanded diameter; and

- 5 a proximal collar and a distal collar, the proximal collar engaged to the proximal waist and the distal collar engaged to the distal waist, each collar being disposed about the catheter shaft and having a nonactivated state and an activated state, wherein in the nonactivated state each collar is freely rotatable about the catheter shaft and in the activated state each collar is contracted to sealingly engage the outer surface of the catheter shaft.